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Amidst Review, EPA Scientists Defend Finding On TCE's Heart-Defect Risks

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In the midst of an EPA headquarters review, EPA and other government scientists are rallying behind the agency's recent risk finding that exposure to the solvent trichloroethylene (TCE) causes cardiac birth defects, saying in a series of recent publications that the evidence of such risks is "strong" or has been "confirmed" by recent science.

Industry scientists and others say the agency's decision, in its 2011 Integrated Risk Information System (IRIS) assessment for TCE, to list cardiac birth defects as a non-cancer endpoint is based on flawed science and should not be used for regulatory purposes because it drives costly and unnecessary protections against short-term exposures.

Already EPA regions and states are adopting competing approaches for how to consider and address the potential risks, creating uncertainty for industry. Some industry officials have called for top waste and research officials in headquarters to intervene, including by conducting a weight-of-evidence review of the risk assessment.

Top EPA headquarters officials are currently conducting such a review.

But now a top EPA scientist responsible for the IRIS assessment is strongly backing the underlying finding. "A broad spectrum of information from thousands of scientific studies" points to a series of non-cancer risks of TCE including risks to a developing fetus, according to an article published late last year in *Environmental Health Perspectives* (EHP) by a group of scientists led by Weihsueh A. Chiu, EPA's chemical manager for TCE.

There is "strong evidence, based on weakly suggestive epidemiologic studies, limited experimental animal studies, and multiple mechanistic studies, that TCE causes fetal cardiac malformations," the scientists say in the paper, "Human Health Effects of Trichloroethylene: Key Findings and Scientific Issues."

In addition, the Agency for Toxic Substances & Disease Registry (ATSDR) is backing EPA's science in health assessments it is conducting at contaminated sites, where it is generally using EPA's reference dose (RfD) and reference concentration (RfC) values as benchmarks to determine risks.

"The major milestones for fetal cardiac development in humans occur over a period of approximately 3 weeks. Therefore, it is appropriate to apply RfD and RfC to pregnant women and women of reproductive age over any three-week period of exposure to consider developmental toxicity," ATSDR says in a response to comments included in its Feb. 13 Health Consultation that found risk of cardiac birth defects from the once-contaminated municipal water supply in Millsboro, DE.

ATSDR completed the assessment over the objections of the Halogenated Solvents Industry Alliance, Inc. (HSIA), whose members include TCE manufacturers. HSIA had asked ATSDR to wait for the results of an ongoing review by the Alliance for Risk Assessment, a private sector group that is critical of EPA's TCE assessment, before finalizing the health consultation, and also criticized ATSDR's use of chronic values from IRIS to calculate protections from acute exposures from TCE for local residents.

And in a July 2012 Health Consultation at a contaminated site in Dracut, MA, recently used as a children's recreation facility, ATSDR says recent science confirms "that cardiac effects are the appropriate toxicological endpoint in humans."

IRIS Assessment

At issue is EPA's IRIS assessment for TCE, which set an RfC -- or the greatest amount of a substance EPA anticipates can be inhaled daily over a lifetime without causing adverse health effects -- of 2 micrograms per cubic meter (ug/m^3), and also included a risk of cardiac birth defects.

Although industry has said the RfC is overly conservative and will slow risk assessments and stall property transactions, much of the controversy has focused on EPA's reliance on Paula D. Johnson's 2003 study on rats that suggests TCE causes fetal cardiac malformations, a developmental risk that implies dangers from short-term exposure. Several peer review panels backed EPA's use of the Johnson study, though industry has criticized it as flawed.

Since issuance of the assessment, EPA regional officials, state regulators and consultants have been scrambling for months for information on how to derive from the RfC, which offers chronic risk protections, regulatory limits to protect against acute or short-term exposures.

Controversy began last spring when EPA's Region IX proposed an interim removal action level (RAL) of 15 micrograms per cubic meter (ug/m^3) for the Middlefield-Ellis-Whisman Superfund site in Mountain View, CA, a limit industry argued is overly conservative, and which prompted calls for the headquarters review.

Sources close to the situation have said industry was likely driven by fears the RAL would open the door to strict new cleanup requirements and bolster future personal injury and worker protection claims that might be brought against private and federal responsible parties at the many sites across the country with TCE contamination including more than 700 Superfund sites.

Since then, at least two other EPA regions as well as state regulators in New Jersey and Massachusetts have employed different limits. The limits range from Massachusetts' use of the RfC to protect pregnant women against residential exposures, to a Region III approach where regulators have ordered evacuations from buildings when indoor air levels of TCE reached 27 ug/m^3.

Region X uses a limit of 2 ug/m^3 at residences and 8.4 ug/m^3 for industrial settings, with both limits averaged over a 21-day exposure period.

While regulators struggle to determine how to proceed, scientists and health officials are standing by the science.

In their December EHP article, the EPA scientists say TCE is carcinogenic to humans through all exposure routes, and that it also carries a host of non-cancer risks other than cardiac birth defects, including hazards affecting the central nervous system, kidney, liver, immune system and male reproductive system.

To support the inclusion of a risk of cardiac defects, the EPA authors cite the 2006 findings by the National Academies' National Research Council (NRC) that "epidemiological studies, although individually limited, as a whole show relatively consistent elevations for cardiac malformations" from TCE exposures.

Interpretation of the data has been controversial, the authors say, since many studies are limited by few cases and insufficient exposure characterization, as well as methodological deficiencies. The EPA authors cite methodological factors as a possible reason for the inability to replicate findings of rodent studies, including the controversial 2003 Johnson study, but add that other types of studies, including bird and epidemiological studies in humans also suggest a risk of cardiac defects.

"Overall, the avian and in vitro data substantially increase the biological plausibility for TCE-induced cardiac [birth defects], and thus strongly support the more limited epidemiologic and in vivo rodent data suggesting that TCE induces cardiac [birth defects]," the EPA authors say.

And in its two site assessments, ATSDR also generally backed EPA's science. In its July 2012 Health Consultation of the Navy Yard Mills Site in Dracut, MA, ATSDR relies on IRIS to assert that pregnant women who either work, exercise or watch youth baseball practice in buildings at the former cotton and woolen mill site may be at risk of having a child with heart problems.

Indoor Air Data

The review of indoor air data included maximum TCE measurements in rooms varying from 6 ug/m^3 to 160 ug/m^3, and ATSDR calculated risks at exposure durations ranging from 10 hours a day, five days a week over several weeks for workers, to visits of more than 10 hours a week to watch baseball practice, depending on which room of the facility the exposures occurred.

In assessing the risk, ATSDR cites the EPA IRIS assessment's reliance on a pair of animal studies used to calculate the RfC, and says EPA used pharmacokinetic modeling to predict a small risk of fetal heart malformations for pregnant women exposed to TCE at 21 ug/m^3, and then EPA used an uncertainty factor of 10 to obtain its RfC of 2 ug/m^3.

ATSDR also relied on the EPA IRIS in finding increased risk of non-cancer health hazards including cardiac birth defects and kidney effects from the roughly one-year exposure to TCE at Millsboro, DE, that occurred sometime between 2004 and 2005 before the contamination from a poultry vaccine manufacturing plant was mitigated.

The Millsboro Health Consultation, which was finalized Feb. 13 over the objections of industry groups, also found increased risk of cancer but ATSDR says the risk is low. The health consultation concludes that pregnant women who drank unfiltered water may have suffered increased likelihood of adverse fetal cardiac effects.

Also, while vapor intrusion has not been confirmed as an exposure pathway in Millsboro, ATSDR used information from the studies on which IRIS is based to conclude that pregnant women who inhaled contaminated vapors from shower water possibly have "an increased likelihood" of having a child with a heart problem. -- *Dave Reynolds* (dreynolds@iwpnews.com)

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